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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/735,602

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Hao-Jan Lin

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT

PAPER NUMBER

1636

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/735,602	<b>Applicant(s)</b> LIN ET AL.	
	<b>Examiner</b> Daniel M. Sullivan	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>PTOL-206</u>                           |

### **DETAILED ACTION**

This Office Action is a reply to the Paper filed 28 February 2008 in response to the Non-Final Office Action mailed 27 November 2007. Claims 1-15 were considered in the 27 November Office Action. Claims 1, 6 and 11 were amended and claim 15 was cancelled in the 28 February Paper. Claims 1-14 are pending and under consideration.

### ***Drawings***

Submission for a petition under 37 CFR § 1.84 to accept color drawings is accepted and approved. (See the attached PTOL-206.)

### ***Response to Amendment and Arguments***

#### **Priority**

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

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The disclosure of the prior-filed application, Application No. 60/444,775, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

In the 28 February 2008 Paper, claims 1 and 11 have been amended to recite providing a gas to the pressurized chamber until the gas establishes a pressure equal to or lower than 100 psi. However, the disclosure of the '775 application does not disclose a range of "equal to or lower than 100 psi" (i.e., 0-100 psi) as now claimed. The provisional application discloses the method wherein naked DNA bombardment is carried out at a helium pressure of 100 psi (see e.g., page 3) or 50 psi (see, e.g., page 4) and protein bombardment is carried out at a helium pressure of 100 psi (see, e.g., page 5). The disclosure of these two points would not convey to one of ordinary skill in the art a range of pressures that might include any value equal to or less than 100 psi. Therefore, the range presently claimed is not supported by the priority application and the claims are not entitled to benefit of the '775 application filing date.

It is additionally noted that the limitations "nitrogen gas" recited in claims 10 and 11, "a speed of 200-300 m/s" recited in claims 7 and 12, "pressure at the sprayer's outlet is about 1 atmospheric pressure" recited in claims 8 and 13, and " $\theta < 15$  degrees" recited in claims 9 and 14 are also not supported by the disclosure of the '775 application.

#### Claim Rejections - 35 USC § 112

Rejection of claim 6 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is **withdrawn** in view of the claim amendments.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 and 7-15 **stand rejected** and claim 6 is **newly rejected** under 35 U.S.C. 103(a) as being unpatentable over Lin et al. (August, 2002) US Patent No. 6,436,709 B1 (previously made of record) in view of Tomalia et al. (January, 2002) US Pub. No. 2002/0013283 A1. (Please note that, in view of the 12 December 2003 filing date afforded the

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instant claims, the Lin et al. patent qualifies as prior art under 102(b). Therefore, the present rejection cannot be overcome under the provisions of 35 USC § 103(c).)

This rejection is maintained for the reasons set forth in the 27 November Office Action (beginning at page 13) and herein above regarding the priority date for the claims of the instant application. This rejection is newly applied to claim 6 in view of the amendment of the claim such that it no longer requires that the immunogen be "for cancer immunotherapy". As described in the *prim a facie* rejection, "Tomalia et al. teaches that viruses, viral fragments, DNA, proteins, etc. can be delivered using the carriers disclosed therein..." (paragraph bridging pages 16-17 of the 27 November Office Action). As any of those agents are immunogenic, the teachings of Lin et al. in view of Tomalia et al. render obvious the invention of amended claim 6 as a whole for the reasons set forth in the previous Office Action.

#### *Response to Arguments*

In the remarks filed in the 28 February Paper, Applicant submits that the present application claims the priority benefits of U.S. provisional application filed on February 3, 2003 (No. 601444,775) while the Lin reference is patented on August 20, 2002, which is not one year earlier than the priority date. Therefore, Applicant contends, Lin is an invalid prior art reference qualified under 35 U.S.C. 102(b).

This argument has been fully considered but is not deemed persuasive. First, for the reasons set forth herein above regarding the priority date for the claims, Lin et al. still qualifies as prior art under 35 USC § 102(b). In addition, even if the claims had been afforded the priority date of the provisional application, Lin et al. would still qualify as prior art under 35 USC §

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102(a) and (e) because the patent names an inventive entity that is different from the inventive entity named on the instant application. As the 28 February submission fails to establish that the prior art subject matter and the claimed invention were owned by or subject to an obligation of assignment to the same person at the time the invention was made as required to exclude art under the provisions of 35 USC § 103(c), the claims would still be properly rejected under 35 USC § 103(a) even if the claims were entitled to benefit of the provisional application. (See MPEP 2146.)

Rejection of claim 6 under 35 U.S.C. 103(a) as being unpatentable over Lin et al. (*supra*) in view of Tomalia et al. (*supra*), as applied to claim 1 herein above, and further in view of Wu et al. (2001) WO 01/29233 A2 is **withdrawn** in favor of the new rejection set forth herein above. As the claims no longer require that the immunogen have the capacity to provide an immune response against a cancer cell, the teachings of Wu et al. are no longer required to render the claimed invention obvious.

### ***New Grounds Necessitated by Amendment***

#### **Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The MPEP states, “If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. §112, first paragraph-written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).” (MPEP §2163.06). The MPEP further states, “Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in the application” (*Id.*, §2163.02). The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996).

In the instant case, independent claims 1 and 11 have been amended to recite that the chamber is pressurized “to establish a pressure equal to or lower than 100 psi”. In support of the limitation, Applicant cites paragraph 0041, lines 3-5 and paragraph 0063, lines 15-16. However, the passage in paragraph 41 contemplates a range delimited as “around 90-100 psi” and the passage in paragraph 0063 contemplates a single point at 100 psi. Neither these specific



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teachings nor the remainder of the original disclosure considered as a whole would have conveyed to one of ordinary skill in the art a range of pressures defined as equal to or lower than 100 psi (i.e., 0-100 psi) as the only range contemplated is from 90 to 100 psi and there is no disclosure at all of the method practiced at a pressure lower than 50 psi (paragraph 0061). In view of this, the range of “equal to or lower than 100 psi” is not supported by the application disclosure as originally filed.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779.

The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel M Sullivan/  
Primary Examiner, Art Unit 1636